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Substitute for form 1449A/PTO

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1568 U.S. PTO  
01/11/66**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet	1	of	16	Attorney Docket Number	MIT 7513/7804
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**U.S. PATENT DOCUMENTS**

Examiner's Initials*	Cite No. <sup>1</sup>	US Patent Document		Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
KES	-	2,470,296		Fields	5/17/49	427/213.31
	-	2,533,065		Taplin, et al	3/8/47 050	424 497
	-	2,992,645		Fowler	7/18/61	128/203.21
	-	3,781,230		Vassiliades, et al	12/25/73	206/387.1
	-	3,957,965		Hartley, et al.	05 04/18/76	424/452
	-	4,009,280		Macarthur, et al.	02/22/77	514/456
	-	4,089,800		Temple	05 04/16/78	427/213.31
	-	4,161,516		Bell	07/17/79	424/451
	-	4,173,488		Vassiliades, et al.	11/06/79	106/216.1
	-	4,272,398		Jaffe	06/09/81	427/213.31
	-	4,352,883		Lim	10/05/82	435/178
	-	4,391,909		Lim	07/05/83	435/1.1
	-	4,466,442		Hilmann, et al.	08/21/84	600/431
	-	4,524,769		Wetterlin	06/25/85	128/203.15
	-	4,572,203		Feinstein	02/25/86	424/9.52
	-	4,590,206		Forrester, et al.	05/20/86	514/456
	-	4,615,697		Robinson	10/07/86	424/428
	-	4,679,555		Sackner	07/14/87	128/203.15
	-	4,741,872		De Luca, et al.	04/03/88	264/4.7
	-	4,743,545		Torobin	05/10/88	435/47
	-	4,774,958		Feinstein	10/04/88	424/9.52
	-	4,789,550		Hommel, et al.	12/06/88	424/493
	-	4,818,542		DeLuca, et al.	04/04/89	424/491
	-	4,847,091		Illum	07/11/89	424/455
KES						

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				Application Number	08/971,791
				Filing Date	November 17, 1997
				First Named Inventor	David A Edwards
				Group Art Unit	1616
				Examiner Name	K. Shelbourne
Sheet	2	of	16	Attorney Docket Number	MIT 7513/7804

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KES	4,855,144			Leong, et al.	08/08/89	514/772.3
	4,857,311			Domb, et al.	08/15/89	427/213.31
	4,861,627			Mathiowitz, et al	08/29/89	364/122
	4,865,789			Castro, et al.	09/12/89	424/490
	4,904,479			Illum.	02/27/90	131/273
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	4,976,968			Steiner	12/11/90	424/497
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	5,123,414			Unger	06/23/92	424/487
	5,160,745			DeLuca, et al.	11/03/92	521/64
	5,169,871			Hughes, et al.	12/08/92	600/438
	5,195,520			Schlieff, et al.	03/23/93	424/434
	5,204,108			Illum	04/20/93	424/454
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	5,260,306			Boardman, et al.	11/09/93	427/213.31
	5,271,961			Mathiowitz, et al.	12/21/93	128/203.12
	5,327,883			Williams, et al.	07/12/94	424/9.51
	5,334,381			Unger	08/02/94	424/9.51
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				Group Art Unit	1616
				Examiner Name	K. Shelbourne
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KES	5,384,133			Boyes, et al.	01/24/95
	5,393,524			Quay	02/28/95
	5,407,609			Tice, et al.	04/18/95
	5,456,917			Wise, et al.	10/10/95
	5,478,578			Arnold, et al	12/26/95
	5,482,946			Clark, et al.	01/09/96
	5,518,709			Sutton, et al.	04/21/96
KES	5,607,695			Ek, et al.	03/04/97

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Examiner's Initials*	Cite No. <sup>1</sup>	Foreign Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
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KES			0 072 048	EPA	02/16/83
			0 213 303	EPA	06/23/86
			0 257 915	EP	03/02/88
			0 324 938	EPA	07/26/89
			0 458 745	EPA	05/14/91
			0 335 133	EP	10/04/89
			1 288 583	GB	11/17/69
			WO 80/02365	PCT WO	11/13/80
			WO 88/04556	PCT WO	06/30/88
			WO 88/09163	PCT W.O.	12/01/88
KES	-		WO 91/04732	PCT W.O.	04/18/91

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 14560 U.S. PTO <b>01/11/99</b> <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary)		Application Number	08/971,791
Filing Date	November 17, 1997		
First Named Inventor	David A Edwards		
Group Art Unit	1615		
Examiner Name	K. Shelbourne		
Sheet	4	of	16
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Sheet	5	of	16

## OTHER ART -- NON PATENT LITERATURE DOCUMENTS

Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, cit and/or country where published	T <sup>2</sup>
KES		Adjei and Garren, "Pulmonary Delivery of Peptide Drugs: Effect of Particle Size on Bioavailability of Leuprolide Acetate in Healthy Male Volunteers," <u>J. Pharm. Res.</u> , 7(6): 565-569 (1990).	
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		Anderson, "Human Deposition and Clearance of 6 micrometer Particles Inhaled with an Extremely Low Flow Rate" <u>Exp. Lung Res.</u> 21(1): 187-195 (1995)	
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Examiner's Signature	<u>Shelborne</u>		Date Considered <b>6/14/99</b>

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				Group Art Unit	1616
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KES		Carroll, et al. "Gelatin Encapsulated Nitrogen Microbubbles as Ultrasonic Contrast Agents" <u>Investigative Radiology</u> 15: 260-266 (1980).			
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		Damms and Bains, "The Cost of Delivering Drugs without Needles," <u>J. Controlled Release</u> , 8-11 (1996).			
KES		Darquenne, et al. "Two and three-dimensional simulations of aerosol transport and deposition in alveolar zone of human lung". <u>Journal of Applied Physiology</u> Davies et al., "Breathing of half-micron aerosols. I. Experimental..," <u>J. Appl. Physiol.</u> 32:591-600 (1972).			
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		* Doubrow, M., Ed., "Microcapsules and Nanoparticles in Medicine and Pharmacy," CRC Press, Boca Raton, (1992).				
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		Eldridge et al., "Biodegradable microspheres as a vaccine delivery system," <u>Mol. Immunol.</u> , 28: 287-294 (1991).				
		Feinstein, et al. "Two-Dimensional Contrast Echocardiography. I. In Vitro Development and Quantitative Analysis of Echo Contrast Agents" <u>JACC</u> 3(1): 14-20 (1984).				
		Ferin, "Pulmonary Retention of Ultrafine and Fine Particles in Rats" <u>Am. J. Respir. Cell Mol. Biol.</u> 6: 535-542 (1992).				
KES		Findeisen, "Uber das Absetzen kleiner in der Luft suspendierter Teilchen in der menschlichen Lunge bei der Atmung," <u>Pflugers Arch. D. Ges. Physiol.</u> 236:367-379 (1935).				
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Sheet	8	of	16	Attorney Docket Number	MIT 7513/7804

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KES		French, Edwards, and Niven, "The influence of formulation on emission, deaggregation and deposition of dry powders for inhalation," <i>J. Aerosol Sci.</i> , 27: 769-783 (1996).				
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		Gurney, et al. Bioadhesive intraoral release systems: design, testing and analysis" <i>Biomaterials</i> 5: 336-340 (1984)				
		Heyder et al., "Deposition of Particles in the Human Respiratory Tract in the Size Range 0.005-15 micrometers," <i>J. Aerosol Sci.</i> , 17: 811-825 (1986).				
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 <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary)		Application Number	08/971,791
		Filing Date	November 17, 1997
		First Named Inventor	David A Edwards
		Group Art Unit	1615
		Examiner Name	K. Shelbourne
Sheet	9	of	16
		Attorney Docket Number	MIT 7513/7804

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				First Named Inventor <b>David A Edwards</b>	
				Group Art Unit <b>1616</b>	
				Examiner Name <b>K. Shelbourne</b>	
Sheet	10	of	16	Attorney Docket Number	<b>MIT 7513/7804</b>

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	-	Kwok, et al. "Production of 5-15 micrometer Diameter Alginate Polylysine Microcapsules by an Air-Atomization Technique," <i>Pharm Res.</i> 8(3):341-344 (1991).			
	-	Lai, et al. "Protection Against Mycoplasma pulmonis Infection by Genetic Vaccination" <i>DNA and Cell Biology</i> 14(7): 643-651 (1995).			
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	-	Landahl, "On the removal of air-borne droplets by the human respiratory tract: I. The lung," <i>Bull. Math. Biophys.</i> , 12:43-56 (1950).			
<i>KES</i>	-	Langer, "New Methods of Drug Delivery," <i>Science</i> , 249:1527-1533 (1990).			
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				First Named Inventor	David A Edwards
				Group Art Unit	1615
				Examiner Name	K. Shelbourne
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Application Number

08/971,791

Filing Date

November 17, 1997

First Named Inventor

David A Edwards

Group Art Unit

1616

Examiner Name

K. Shelbourne

Attorney Docket Number

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		Rudt et al., " <i>In vitro</i> phagocytosis assay of nano- and microparticles by chemiluminescence. IV. Effect of surface modification by coating of particles with poloxamine and Antarox CO on the phagocytic uptake," <i>J. Contr. Rel.</i> 25:123 (1993).	
KES		Ruffin et al., "The Preferential Deposition of Inhaled Isoproterenol and Propanolol in Asthmatic Patients," <i>Chest</i> 80:904-907 (1986).	
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		Smith, et al. "Aerosol Administration of Antibiotics" <u>Respiration</u> , 62(1) 19-24 (1995).		
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		Tabareta and Ikada, "Effect of size and surface charge of polymer microspheres on their phagocytosis by macrophage," <u>J. Biomed. Mater. Res.</u> , 22:837 (1988).		
		Taburet, et al. "Pharmacokinetic Optimisation of Asthma Treatment" <u>Clin. Pharmacokinet.</u> 26(5): 396-418 (1994)		
KES		* Tansey, "The challenges in the development of metered dose inhalation aerosols using ozone-friendly propellants," <u>Spray Technol. Market</u> , 4:26-29 (1994).		
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 010 66/11/10 Substitute for form 1449A/PTO	Complete if Known				
	Application Number	08/971,791			
			Filing Date	November 17, 1997	
			First Named Inventor	David A Edwards	
			Group Art Unit	1615	
			Examiner Name	K. Shelbourne	
Sheet	15	of	16	Attorney Docket Number	MIT 7513/7804

OTHER ART -- NON PATENT LITERATURE DOCUMENTS					
Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, cit and/or country where published			
KES		Timsina et al., "Drug delivery to the respiratory tract using dry powder inhalers," <u>Int. J. Pharm.</u> , 101: 1-13 (1994).			
		Turner, J. and S. Hering, "Greased and oiled substrates as bounce-free impaction surfaces," <u>J. Aerosol Sci.</u> , 18: 215-224 (1987).			
		* Vincent, <u>Aerosol Science for Industrial Hygienists</u> , Pergamon Press, NY (1995).			
		Visser, "An Invited Review: Van der Waals and Other Cohesive Forces Affecting Powder Fluidization," <u>Powder Technology</u> 58: 1-10 (1989).			
		Wall, "Pulmonary Absorption of Peptides and Proteins," <u>Drug Delivery</u> , 2:1-20 (1995).			
		Warheit and Hartsky, "Role of alveolar macrophage chemotaxis and phagocytosis in pulmonary clearance to inhaled particles: Comparisons among rodent species," <u>Microscopy Res. Tech.</u> , 26: 412-422 (1993).			
		Wheatley, et al. "Contrast agents for diagnostic ultrasound: development and evaluation of polymer-coated microbubbles" <u>Biomaterials</u> 11: 713-717(1990).			
		* Weibel, <u>Morphometry of the Human Lung</u> , New York: Academic Press (1963).			
		Wichert, et al. Low molecular weight PLA: a suitable polymer for pulmonary administered microparticles?" <u>J. Microencapsulation</u> , 10: 195-207 (1993).			
		Wong and Suslick, "Sonochemically produced hemoglobin microbubbles," <u>Mat. Res. Soc. Symp. Proc.</u> , 372:89-95 (1995).			
KES		Zanen et al., "The optimal particle size for β-adrenergic aerosols in mild asthmatics," <u>Int. J. Pharm.</u> , 107: 211-217 (1994).			
Examiner's Signature	Shelborne				6/14/99

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary)			
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		Filing Date	November 17, 1997
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